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Substitute for form 1449A/PTO	Com	Complete if Known		
· ·	Application Number	10/747,685		
INFORMATION DISCLOSURE	Filing Date	December 30, 2003		
STATEMENT BY APPLICANT	First Named Inventor	STEINER, Mitchell S.		
	Group Art Unit	1614		
(use as many sheets as necessary)	Examiner Name	Not yet known		
Sheet 1 of 9	Attorney Docket Number	P-2769-US10		

			υ.	S. PATENT DOCUMENTS		
		U.S. Pater	nt Document	Name of Patentas or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant
Examiner Cite Initials* No.1		Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
BF	A	4,990,538		Harris et al.	February 5, 91	
i	В	5,788,964		Baral et al.	August 4, 98	
	С	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	В	5,491,173		Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jaionen et al.	Nov. 5, 1996	
	G	5,605,700		DeGregorio et al.	Feb. 25, 1997	
	н	5,595,722		Grainger et al.	Jan. 21, 1997	
	I	5,599,844		Grainger et al.	Feb. 4, 1997	
	J	5,629,007		Audia et al.	May 13, 1997	
	K	5,635,197		Audia et al.	June 3, 1997	
· .	L	5,595,985		Labrie	Jan. 21, 1997	
1/	М	5,441,986		Thompsan, et al	August, 15, 1995	
$\mathbf{V}_{-}$	N	5, 859, 045		Treppendahl, et al	January 12, 1999	_
BF.	0	5, 935, 987		Treppendahl, et al	August 10, 1999	•

			FOR	EIGN PATENT DOCUM	ENTS		
Examiner Initials*	Cite No.		gnPatent Document  Kind Code <sup>t</sup> Number <sup>a</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
BF	P	wo	98/58634	Degregorio, et al	December 30, 1998		
1	Q	EP	415 623 A2	Harris et al	March 6, 1991		
	R	EP	616 529 B1	Jalonen, et al	September 28,1994		
	s	EPC	095875	Toivola, et al	Dec 7, 1995		
	Т	wo	95/26720	Bicgon et al	Oct 12, 1995		
	υ	wo	0008001	Huebner, et al	Feb 17, 2000	-	
	v	wo	95/26720	Biegon, et al	October 12, 1995		
	w	wo	00/19998	KGK SYNERGIZE	April 13, 2000		
	х	wo	97/25038	NOVO NORDISK	July 17, 1997		
W	Y	wo	99/08682	DUKE UNIVERSITY	February 25, 1999		
BF	z	wo	97/25037	NOVO NORDISK	July 17, 1997		

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STA	ATEME	NT B	Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1614	
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Sheet	2	of	9	Attorney Docket Number	P-2769-US10	

	<del></del>	U.S. Patent Document	.S. PATENT DOCUMENTS		Pages, Columns, Lines,
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BF	AA	4,329,364	Neri et al.	May 11, 1982	
1	AB	4,474,813	Neri et al.	Oct. 2, 1984	
	AC	6,080,877	Swindell et al	June, 2000	
	AD	6,265,448	Steiner et al	July 24, 2001	
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	AF	6,632,447	Steiner et al	Oct 14, 2003	
	AG	6,413,533	Steiner et al	July 2, 2002	
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	AJ	4,996,225	Toivola et al	Feb 26, 1991	
	AK	5,811,120	Gibson et al	Sept 22, 1998	
	AL	5,972,383	Gibson et al	Oct 26, 1999	
$\perp$	AM	4,418,068	Jones	Nov 29, 1983	
V	AN	5,852,059	Thompson, et al	December 22, 1998	
	AO	5,827,892	Loeser, et al	October 27, 1998	
BF	AP	5,821,254	Sporn, et al	October 13, 1998	

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BF	AQ	wo	94/12162	Warri et al	June 9, 1994			
BF	AR	wo	99/56739	Steiner et al	November 11, 1999		$\Box$	
BF	AS	wo	00/47214	Healey et al	August 17, 2000			
BF	AT	wo	96/09046	Audia et al	March 28, 1996			
RP	ΑÜ	EP	0 670 162	Gibson et al	Sept 6, 1995			

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		NON PATENT LITERATURE DOCUMENTS					
Examiner Cite No.1  BF AV		o. 1 publisher, city and/or country where published.					
		Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.					
	AW	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	$\Box$				
	AX	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.					
	AY	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.					
	ΑZ	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.					
	ВА	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265.					
	ВВ	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.					
	вс	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.					
	BD	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997					
	BE	Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc					
	BF	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.					
	BG	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.					
	вн	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.					
V	BI	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.					
BF	BJ	Gershanovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.					

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Signature		Considered	. 01/07/2007

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				Group Art Unit	1614	
(use as many sheets as necessary)		Examiner Name	Not yet known			
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		NON PATENT LITERATURE DOCUMENTS	
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
BF	вк	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BL	Pyrhonen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277	
	ВМ	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	BN	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	во	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
	BP	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	BQ	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997, 11(5 Suppl 4): 37-40.	
	BR	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	BS	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 177- Estadiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	BT	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4- Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	BU	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	BV	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	BW	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	T
	BX	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In	
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BF	BZ	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	

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Signature	_	Considered	

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		Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
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	CE	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate", Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	CF	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.	
	CG	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	CH	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	
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	Cı	Chang William Y et al. "Estrogen Receptor-?: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	CK	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And ? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
	CL	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801-1809, 1997)	
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BF	CP	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138-139 (1992).	
ī	CQ	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-?", Endocrinology Vol. 138, No. 3, (1997).	
	CR	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors? and?", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	CS	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	CT	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	CU	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	
	CV	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	CW	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	CX	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	CY	Karnat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	CZ	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	DA	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
$\sqrt{}$	DB	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
BF	DC	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

Examiner Signature	/Blessing Fubara/	Date Considered	01/07/2007

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BF	DD	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
	DE	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	DF	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research. December 1998	
	DG	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention:, Proc. Nsil. Acad. Sci, USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.	
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Examiner Signature	/Blessing Fubara/	Date Considered	01/07/2007

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO				Complete if Known		
	•			Application Number	10/747,685	
INFO	DRMA	TION	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
•				Group Art Unit	1614	
(use as many sheets as necessary)			ets as necessary)	Examiner Name	Not yet known	
Sheet	8	of	9	Attorney Docket Number	P-2769-US10	

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